K083234

510(k) Summary for the Kimberly-Clark* Corporation KC100 Surgical Drapes and Equipment Covers

MAR 2 5 2009

Date Summary was Prepared:	October 31, 2008
510(k) Submitter:	Thomas Kozma Director, Regulatory Affairs Kimberly-Clark Health Care 1400 Holcomb Bridge Road Roswell, GA 30076 Ph: 770.587.8393 FAX: 920.225.3408 Email: thomas.kozma@kcc.com
Primary Contact for this 510(k) Submission:	Lisa Peacock, Consultant to Kimberly-Clark Health Care SciMed, Inc. Ph: 706.216.3413 FAX: 800.713.7754 Email: lisa.peacock@kcc.com
Device Common Name:	Sterile surgical drapes and surgical equipment covers
Device Product Codes and Classification Names:	KKX Surgical Drapes MMP Protective Barrier Covers
Intended Use:	Kimberly-Clark Corporation intends to market the sterile KC100 Surgical Drapes as devices made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. Kimberly-Clark intends to market the sterile KC100 Surgical Equipment Covers which are protective barrier covers that are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.
Predicate Devices:	K080629 proMedical Surgical Drapes and proMedical Surgical Equipment Covers
Substantial Equivalence:	The surgical drapes and equipment covers described in this 510(k) submission are identical in all specifications to the predicate device models identified in K080629 except for minor variations in the widths and lengths of three models.

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Summary of Testing:

The KC100 Surgical Drapes and Equipment Covers are identical to, and meet the same acceptance testing criteria as, their predicate drapes and covers in K080629. Testing included biocompatibility (i.e., cytotoxicity, irritation, and sensitization) in compliance with the methods of ISO 10993, barrier properties, tensile and tear strength, alcohol repellency, and flammability. All results of testing met acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Kimberly-Clark Corporation
C/o Ms. Lisa Peacock, RAC
Consultant to Kimberly-Clark Health Care
SciMed, Incorporated
172 Conductor Drive
Dawsonville, Georgia 30534

Re: K083234
Trade/Device Name: KC100 Surgical Drapes &
KC100 Surgical Equipment Covers
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: February 23, 2009
Received: February 25, 2009

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083234

Device Name: KC100 Surgical Equipment Covers

Indications for Use:

Kimberly-Clark* Corporation intends to market the sterile KC100 Surgical Equipment Covers which are protective barrier covers that are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

Product Name	Model Code	Cover Materials
Mayo Stand Cover	88656	Blue polyethylene with air-laid reinforcement
Table Cover	88673 88666 89564	Blue polyethylene with air-laid reinforcement

Prescription Use _____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083234

Indications for Use

510(k) Number (if known): K083234

Device Name: KC100 Surgical Drapes

Indications for Use:

Kimberly-Clark* Corporation intends to market the sterile KC100 Surgical Drapes as devices made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. See Page 2 for product list.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083234

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Indications for Use Product List

Product Name	Model Code	Drape Materials
Angiography Surgical Drape	89583	SMS base panel with air-laid pad and polyethylene
Clear Legging Surgical Drape	89195	Polyethylene
Universal Extremity Surgical Drape	89191	SMS base panel with air-laid pad
Legging Surgical Drape	70093855	SMS panel
Head Surgical Drape	70093879	SMS panel
Side Surgical Drape	89556	SMS base panel with air-laid pad
Top Surgical Drape	89554	SMS base panel with air-laid pad
Bottom Surgical Drape	89555	SMS base panel with air-laid pad
Bar Surgical Drape	89533	SMS base panel with air-laid pad
Arthroscopy Surgical Drape	88661	SMS base panel with polyethylene
Under Buttocks Surgical Drape	89584	SMS base panel with air-laid pad and polyethylene
Split EENT Surgical Drape	89197	SMS base panel with air-laid pad
Lithotomy Surgical Drape	89198	SMS base panel with air-laid pad
Laparoscopy T Surgical Drape	89199	SMS base panel with air-laid pad
Thyroid Surgical Drape	89539	SMS base panel with air-laid pad
Minor Procedure Surgical Drape	89531	SMS base panel with air-laid pad
Lap Chole Surgical Drape	89538	SMS base panel with air-laid pad
Cystoscopy T Surgical Drape	89196	SMS base panel with air-laid pad
Chest Surgical Drape	89561	SMS base panel with air-laid pad
Utility Surgical Drape	89536	Air-laid absorbent panel
Split Surgical Drape	89190	Polyethylene
U Surgical Drape	89532	SMS base panel with air-laid pad
Laparotomy Surgical Drape	89537	SMS base panel with air-laid pad
Shoulder Arthroscopy Surgical Drape	89558	SMS base panel with polyethylene
Body Split Surgical Drape	89560	SMS base panel with air-laid pad and polyethylene
Body Split Surgical Drape	89557	SMS base panel with air-laid pad
Half Surgical Drape	89534	SMS panel
Large Surgical Drape	79535	SMS panel
Universal Spine Surgical Drape	89193	SMS base panel with air-laid pad and polyethylene
Dental Surgical Drape	89543	SMS base panel with air-laid pad
Stockinette Surgical Drape	044001-700	Polyethylene stockinette